

### **REMARKS**

The Final Office action dated June 18, 2009 is acknowledged. Claims 1 and 4-35 are pending in the instant application. Specifically, claims 1, 4-8, 17-19, 21, 34 and 35 have been rejected and claims 9-16, 20 and 22-33 have been withdrawn. According to the Final Office action, each of claims 4-8, 17-19, 21, 34 and 35 has been rejected. Claim 17 is amended herewith to depend from claim 1 rather than claim 3, which stands as canceled. The Applicant thanks the Examiner for the acknowledgment that the priority requirement has been perfected in the present case. The Applicant also thanks the Examiner for the withdrawal of the prior objection to claim 1 and rejection to claim 34. Reconsideration is respectfully requested in light of the amendments being made hereby and the arguments made herein. No new matter has been added.

### **Finality of the present Office action**

As explained by the Examiner at page 9 of the Final Office action, all claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Therefore, the Examiner has made the present Office action final even though it is a first action after the filing of a request for continued examination (RCE) and the submission under 37 CFR 1.114.

The Applicant respectfully disagrees with the Examiner's decision to make the present action final. In particular, the Applicant submits that the claims submitted with the RCE were not drawn to the same invention in the application prior to filing the RCE, and – based on the content of the previous Office action – there was no reason to believe

that the amended claim submitted with the RCE could have been finally rejected on the grounds and art of record if they had been entered into the application prior to entry of the RCE.

In the Advisory Action dated March 4, 2009, it was indicated that the amendments to claims 1 and 34 would be persuasive enough to overcome at least the obviousness rejection under Section 103 in view of Whittle, et al., but would not be entered (see “continuation of 3” on page 2 of the Advisory Action dated March 4, 2009). Accordingly, the same amendments were filed with the RCE and entered on the record. In turn, it appears that the Examiner’s position on the previously filed amended claims is now different in the Final Office action from that in the Advisory Action. Accordingly, withdrawal of the finality of the present Office action is strongly requested.

**Rejection of Claims 1-8, 17-19, 21, 34 & 35 Under 35 U.S.C. 103(a)**

Claims 1-8, 17-19, 21, 34 & 35 have been rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Publication No. 2002/0136752 (Whittle, et al.). The Examiner argues that Whittle, et al. disclose the limitations of the presently claimed invention, as discussed in detail on pages 4-7 of the present Final Office action. In particular, the Examiner states that Whittle, et al. teach a film-shaped, pharmaceutical formulation for administration to a mucosal surface, wherein the formulation comprises at least one lipophilic medicament and a matrix which comprises at least one emulsifying agent and a sweetening or flavoring agent. The Examiner acknowledges that Whittle, et al. fail to teach the overall administration form as conforming to the instantly claimed thickness limitations.

In this regard, the Examiner concludes that it would have been obvious to one

skilled in the art to prepare the instantly claimed single- or multi-layered, cannabis extract/cannabinoid mucoadhesive administration form as taught by Whittle, et al. and to modify the thickness of the cast film form to produce the presently claimed invention. The Examiner further concludes that one skilled in the art would have been highly motivated to do so because Whittle, et al. expressly teach each of the aspects of the presently claimed, with the exception of conforming said article to the claimed dimensions. The Examiner also states that it would have been *prima facie* obvious to one skilled in the art to optimize the thickness parameter of the administration forms for any number of reasons related to the efficacy or aesthetic aspects of the invention (i.e., to be able to accommodate the variety of different oral or buccal locations to which the form will be applied).

The Applicant respectfully submits that to establish a *prima facie* case of obviousness, three basic criteria must be met, as set forth in M.P.E.P. § 2142. First, there must be some suggestion or motivation to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The Applicant respectfully disagrees with the Examiner's conclusion set forth in the Final Office action. As noted above, the Examiner has now concluded that the subject matter of the amended claims is not patentable over Whittle, et al., despite a contrary statement in the Advisory Action. Regarding the polymer composition, it is stated in the present Final Office action that the composition of Example 9 of Whittle, et al. teaches the instantly claimed water-soluble polymer limitation of claims 3 and 17

whereby it contains gum acacia (e.g., a water-soluble natural gum). It is noted that claim 3 has been canceled in a previous Office action response and claim 17 has been amended to depend from claim 1. The polymer matrix as presently defined in claim 1 does not contain gum acacia due to the definition of the Markush group.

In the “Response to Arguments” section, the Examiner indicates that the Whittle, et al. reference recites hydroxypropyl cellulose which is also recited in present claim 1. The Examiner further considers that hydroxypropyl cellulose is functionally equivalent to acacia gum. This is contested since Whittle, et al. teach (on page 6, Table 2) that acacia forms a viscous coacervate with positively charged gels, such as gelatins. Conversely, this means that acacia does not form a viscous coacervate when not combined with a positively charged gel. Table 2 of Whittle, et al. lists the following groups of substances:

- negatively charged gelling agents (Acacia, pregelatinised starch);
- positively charged gelling agents (gelatin);
- emulsifiers;
- solubilisers;
- viscolisers;
- others (stabilizers, wetting agents).

Acacia is described as forming a viscous coacervate with positively charged gels such as gelatin (see Table 2, comments). The Applicant submits that “forming a viscous coacervate with positively charged gels” is not equivalent to being a “viscoliser.” Accordingly, acacia gum is not labeled as a “viscoliser” in the Comments of Table 2.

The Examiner has suggested in the Office action that the skilled artisan would have been motivated to substitute hydroxypropyl cellulose for acacia. However, acacia is

a negatively charged substance whereas hydroxypropyl cellulose does not have any charged groups, i.e., this polymer has a neutral charge. Therefore, if acacia was replaced with hydroxypropyl cellulose, gel formation by coacervation (which is regarded as an essential feature by Whittle, et al. (paragraph [0029])) would not be possible. Apart from that, the skilled person, in general, would hesitate to replace a charged polymer with a polymer having a neutral surface charge since the difference in surface charge would be expected to result in differing physico-chemical properties. Therefore, neither the teaching of Whittle, et al., nor general technical knowledge, could provide a basis for the Examiner's allegation suggesting that hydroxypropyl cellulose and acacia gum could be regarded as functional equivalents.

Regarding the alleged functional equivalence of hydroxypropyl cellulose and acacia gum, the Examiner has further generally referred to the Examples of the reference. However, none of the compositions of the Examples of Whittle, et al. could support the Examiner's conclusion. While some of the exemplary compositions contain acacia gum, none of these compositions contains hydroxypropyl cellulose.

In view of the above, the teachings of Whittle, et al. fail to make the presently claimed invention obvious. It is therefore respectfully submitted that the present invention defined in the present claims is patentably distinguishable over the prior art teachings under 35 U.S.C. 103(a). Based on the aforementioned differences, each and every element of the present invention recited in the present claims is not set forth in Whittle, et al., nor would one skilled in the art be motivated to modify Whittle, et al. to arrive at the presently claimed invention. Therefore, the Applicant respectfully requests that this rejection be withdrawn.

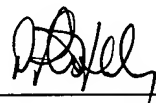
### Conclusion

For the foregoing reasons, it is believed that the present application, as amended, is in condition for allowance, and such action is earnestly solicited. Based on the foregoing arguments, amendments to the claims and deficiencies of the prior art references, the Applicant strongly urges that the obviousness-type rejection and anticipation rejection be withdrawn. The Examiner is invited to call the undersigned if there are any remaining issues to be discussed which could expedite the prosecution of the present application.

Respectfully submitted,

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D. Peter Hochberg Co., L.P.A.  
1940 East 6<sup>th</sup> Street, 6<sup>th</sup> Floor  
Cleveland, OH 44114  
(216) 771-3800

By:   
D. Peter Hochberg  
Reg. No. 24,603